IAP15 Rec'd PCT/PTO 04 DEC 2006

PTO/SB/21 (09-06)

Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

		Application Number	10/591,371	l		
TRANSMITTAL		Filing Date	09/01/2006	2006		
FORM		First Named Inventor	RUSSWUF	RM		
		Art Unit	1623	1623		
(to be used for all correspondence after initial	filing)	Examiner Name	Unassigne	Unassigned		
Total Number of Pages in This Submission		Attorney Docket Number	3535-022			
	ENC	LOSURES (Check al	l that apply			
			т шас арргу		Allowance Communication to TC	
Fee Transmittal Form Fee Attached		Drawing(s) Licensing-related Papers			al Communication to Board	
Amendment/Reply After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53		Petition Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Address Terminal Disclaimer Request for Refund CD, Number of CD(s) Landscape Table on CD		of Appeals and Interferences Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) Proprietary Information Status Letter Other Enclosure(s) (please Identify below): Forms PTO/SB/08B; copies of cited references.		
·	TURE C	OF APPLICANT, ATTO	DRNEY, C	R AGENT	·	
Firm Name Akerman Senterfitt / Cust	omer No.	30448				
Signature Nickels.	. 4	mdan				
Printed name Nicholas J. Landau						
Date 12/01/2006			Reg. No.	57,120		
	CERTIFICATE OF TRANSMISSION/MAILING					
I hereby certify that this correspondence is sufficient postage as first class mail in an er the date shown below:	being facsi nvelope ad	mile transmitted to the USP dressed to: Commissioner for	TO or depos or Patents, F	ited with the Ur P.O. Box 1450,	nited States Postal Service with Alexandria, VA 22313-1450 on	
Signature	a J	T. Landan				
Typed or printed name Nicholas J. Land	-			Date	12/01/06	
					•	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14: This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of RUSSWURM, et al.

Confirmation No. 7019

Application No. 10/591,371

Examiner: Unassigned

Filed: September 1, 2006

Group Art Unit: 1623

Attorney Docket No. 3535-022

For:

METHOD FOR THE IDENTIFICATION OF SEPSIS

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313-1450 on

Michalay Candage No. 5

Nicholas J. Landau, Ph.D.

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56, Applicants hereby notify the U.S. Patent Office of the documents which are listed on the attached Forms PTO/SB/08B.

Applicants submit that the present invention is patentable over the cited references and submission of the listed documents is not intended as an admission that such documents constitute prior art against the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove the listed documents as competent references against the present application. The references were cited in the specification of the present application. Insofar as the references are relevant, their relevance is explained in the Specification.

{WP353384;1}

Attorney Docket No. 3535-022

Application No. 10/591,371 Information Disclosure Statement

Page 2 of 2

Applicants respectfully request that the listed documents be considered by the Examiner

and made of record in the present application and that an initialed copy of forms PTO/SB/08B be

returned in accordance with MPEP §609.

Certification

This Statement is being filed prior to the issuance of the first Office Action for the present

application, and this paper is thus submitted in accordance with 37 C.F.R. 1.97(b).

In view of the above certification, a fee is not required for consideration of this document.

Nevertheless, should a fee be deemed to be due by the Commissioner, such fee should be charged

to Deposit Account No. 50-0951.

Respectfully submitted,

Dated: December 1, 2006

Nicholas J. Landau, Ph.D.

Reg. No. 57,120

AKERMAN SENTERFITT

Post Office Box 3188

West Palm Beach, FL 33402-3188

Tel: 561-653-5000

Docket No. 3535-022

PTO/SB/08B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
b a collection of information unless it contains a valid OMB control number.

Substitu	ite for form 1449/PTO				Complete if Known
Substitu	040000000000000000000000000000000000000		Application Number	10/591,371	
			CLOSURE	Filing Date	09/01/2006
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	RUSSWURM
	(lica as many she	ate ac n	ocassary)	Art Unit	1623
	(Use as many sheets as necessary)			Examiner Name	Unassigned
Sheet	1.	of	5	Attorney Docket Number	3535-022

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ABRAHAM, et al., "Lenercept (p55 tumor necrosis factor receptor fusion protein) in severe sepsis and early septic shock: A random", Crit Care Med 29(3): 503-510 (2001).	
		ABRAHAM, et al., "Sepsis Therapy Trials: Continued Dissappointment or Reason to Hope?", JAMA, 271(23): 1876-1878 (1994).	
		ABRAHAM, et al., "Assessment of the safety recombinant tissue factor pathway inhibitor in patients with severe sepsis", Crit Care Med, 29(11): 2081-2089 (2001).	
		ABRAHAM, et al., "Sepsis and mediator-directed therapy: rethinking the target populations", Molecular Medicine Today, 56-58 (1999).	
		ALBERTI, et al., "Influence of Systemic Inflammatory Response Syndrome and Sepsis on Outcome of Critically III Infected Patients", Am J Respir Crit Care Med, 168:77-84 (2003).	
		ALIZADEH, et al., "Distinct types of diffuse large B-cell lymphoma identified by gene expression profiling", Nature, 403: 503-511 (2000).	
		BEUTLER, et al., "Sepsis and evolution of the innate immune response", Crit Care Med, 29(7) Suppl.: S2-S7 (2001).	
		BONE, et al., "The ACCP/SCCM Consensus Conference on Sepsis and Organ Failure", 101(6): 1481-1483 (1992).	
		BONE, ROGER C., "Sepsis, the Sepsis Syndrome, Multi-Organ Failure: A Plea for Comparable Definitions", Annals of Internal Medicine, 114(4): 332-3 (1991).	
		BONE, ROGER C., "The Pathogenesis of Sepsis", Annals of Internal Medicine, 115: 457-469 (1991).	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

Considered, Include reference considered, whether or not citation is in conformance with MPEP 609. Draw line inrough citation in not in conformance and not considered, include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	e for form 1449/PTO	1449/PTO			Complete if Known
Substitut	e 101 101111 1449/1-10			Application Number	10/591,371
INFO	ORMATION	DIS	CLOSURE	Filing Date	09/01/2006
STA	TEMENT E	BY A	PPLICANT	First Named Inventor	RUSSWURM
				Art Unit	1623
(Use as many sheets as necessary)		Examiner Name	Unassigned		
Sheet	2	of	5	Attorney Docket Number	3535-022

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		BRUN-BUISSON, et al., "Incidence, Risk Factors, and Outcome of Severe Sepsis and Septic Shock in Adults", JAMA 274(12): 968-974 (1995).	
		BRUN-BUISSON, et al., "The costs of septic syndromes in the intensive care unit and influence of hospital-acquired sepsis", Intensive Care Med, 29: 1464-1471 (2003).	
		EILING, et al., "Indentification of differentially expressed genes during systemic inflammatory response syndrome using cDNA microarrays", Infection, 31: 301 (2003).	
1		FILLION, et al., "Role of Chemokines and Formyl Peptides in Pneumococcal Pneumonia-Induced Monocyte/Macrophage Recruitment", Journal of Immunology, 166: 7353-7361 (2001).	
		FODOR, et al., "Light-Directed, Spatially Addressable Parallel Chemical Synthesis", Science, 215: 767-773 (1991).	
		FRIEDLAND, et al., "Plasma proinflammatory cytokine concentrations, Acute Physiology and Chronic Health Evaluation (APACHE)", Crit Care Med, 24(11): 1775-1781 (1996).	
		GILLESPIE, et al., "A Quantitiative Assay for DNA-RNA Hybrids with DNA immobilized on a Membrane", J. Mol. Biol., 12: 829-842 (1965).	
		GOLUB, et al., "Molecular Classification of Cancer: Class Discovery and Class Prediction by Gene Expression Monitoring", Science, 286: 531-537 (1999).	
		HENRY, et al., "Chipping away at brain function: mining for insights with microarrays", Current Opinion in Nuerobiology, 13: 570-576 (2003).	
		HUBER, et al., "Parameter estimation for the calibration and variance stabilization", Statistical Applications in Genetics and Molecular Biology, 2(1): 1-22 (2003).	

	· · · · · · · · · · · · · · · · · · ·		
Examiner		Date	
Signature		Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Linday the Panaguark Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMR control number

Substitu	Substitute for form 1449/PTO INFORMATION				Complete if Known
Substitu	10 10 10 11 144 <i>9 1</i> 10			Application Number	10/591,371
INF	ORMATION	I DIS	CLOSURE	Filing Date	09/01/2006
STA	STATEMENT BY APPLICANT		First Named Inventor	RUSSWURM	
	(11			Art Unit	1623
	(Use as many sh	eets as n	ecessary)	Examiner Name	Unassigned
Sheet	3	of	5	Attorney Docket Number	3535-022

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		"Increase in National Hospital Discharge Survey Rates for SepticemiaUnited States, 1979-1987", MMWR Morb Mortal Wkly Rep, 39(2): 31-34 (1990).	
		KAFATOS, et al., "Determination of nucleic acid sequence homologies and relative concentrations by a dot hybridization", Nucelic Acids Research, 7(6): 1541-1552 (1979).	
		LE GALL, et al., "Customized Probability Models for Early Severe Sepsis in Adult Intensive Care Patients", JAMA, 273(8): 644-650 (1995).	
		LENNON, et al., "Hybridization analyses of arrayed cDNA libraries", Trends Genet, 7(10): 314-317 (1991).	
		LEVY, et al., "2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference", Crit Care Med, 31(4): 1250-1256 (2003).	
		MARSHALL, et al., "SIRS AND MODS: WHAT IS THEIR RELEVANCE TO THE SCIENCE AND PRACTICE OF INTENSIVE CARE?", Shock, 14(6): 586-589 (2000).	
		MARSHALL, et al, "Measures, markers and mediators: Toward a staging system for clinical sepsis. A Report of the Fifth Toronto Sepsis", Crit Care Med, 31(5): 1560-67 (2003).	
		MATOT, et al., "Definition of sepsis", Intensive Care Med, 27:S3-S9 (2001).	
		PATHAN, et al., "Role of interleukin 6 in myocardial dysfunction of meningococcal spetic shock", Lancet, 363: 203-209 (2004).	
		PEASE, et al., "Light-generated oligonucleotide arrays for rapid DNA sequence analysis", Proc. Natl. Acad. Sci., 91: 5022-5026 (1994).	

Examiner	,	Date	
Signature		Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
by a collection of information unless it contains a valid OMB control number.

Substitu	bstitute for form 1449/PTO VFORMATION DISCLOSURE			Complete if Known			
Substitu	te for form 1449/F10			Application Number	10/591,371		
INFO	ORMATIO	V DIS	CLOSURE	Filing Date	09/01/2006		
STA	STATEMENT BY APPLICANT			First Named Inventor	RUSSWURM		
	(Use as many sheets as necessary)			Art Unit	1623		
	(Use as many sr	ieets as n	lecessary)	Examiner Name	Unassigned		
Sheet	4	of	5	Attorney Docket Number	3535-022		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		PITTET, et al., "Impact of Immunomodulating Therapy on Morbidity in Patients with Severe Sepsis", Am J Respir Crit Care Med 160: 852-857 (1999).	
		POEZE, et al., "An international sepsis survey: a study of doctors' knowledge and perception about sepsis", Critical Care, 8(6): R409-R413, 1-6 (2004).	
		RUSSWURM, et al., "PROCALCITONIN AS MONOCYTE MARKER FOR EARLY DIAGNOSIS OF SEPTIC ABORTION", Z Geburtsh Neonatol, 204: 34-38 (2000).	
		RUSSWURM, S., "Procalcitonin as a Marker of Bacterial Infections and Sepsis: Effect of Sepsis-Relevant Conditions on the Expression of Procalcitonin", 1-44 (2002).	
		SCHENA, et al., "Quantitative Monitoring of Gene Expression Patterns with a Complementary DNA Microarray", Science, 270: 467-469 (1995).	
		SOUTHERN, E.M., "An Improved Method for Transferring Nucleotides from Electrophoresis Strips to Thin Layers of Ion-Exchange" Analytical Biochemistry, 62: 317-8 (1974).	
		STRAUBE, E., "Sepsis - microbiological diagnosis", Infection, 31(4): 284-5 (2003).	
		VINCENT, J., "Dear SIRS, I'm sorry to say that I don't like you", Crit Care Med, 25(2): 372-374 (1997).	
		VINCENT, et al., "Clinical expert round table discussion (session 5) at the Margaux Conference on Critical Illness", Crit Care Med, 29(7) Suppl.: S136-S137 (2001).	
		ZENI, et al., "Anti-inflammatory therapies to treat sepsis and septic shock: A reassessment", Crit Care Med, 25(7): 1095-1100 (1997).	

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (09-06) Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449/PTO Complete if Known							
Substitute for form 1449/FTO				Application Number	10/591,371		
INFORMATION DISCLOSURE				Filing Date	09/01/2006		
STATEMENT BY APPLICANT				First Named Inventor	RUSSWURM		
(Use as many sheets as necessary)				Art Unit	1623		
			ecessary)	Examiner Name	Unassigned		
Sheet	5	of	5	Attorney Docket Number	3535-022		

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹				
		ZHAO, et al., "Human endothelial cell reponse to gram-negative lipopolysaccharide assessed with cDNA microarrays", Am J Physiol Cell Physiol, 281: C1587-C1595 (2001).			
i					
	<u> </u>	<u> </u>	<u> </u>		

Examiner	Date	
Signature	 Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.